Atty. Dkt. No. 062287-2120

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Thomas A. SILVESTRINI

Title: SEGMENTED PLIABLE INTRASTROMAL CORNEAL INSERT

Appl. No.: 08/596,221

Filing Date: July 16, 1996

Examiner: David H. WILLSE

Art Unit: 3738

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BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
P.O. Box 1450
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02-06-2006
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Sir:

On December 5, 2005, Applicant filed a Notice of Appeal to the Board of Patent Appeals and Interferences in connection with the above-identified application, making the Brief or other action due February 5, 2006. However, because February 5, 2006 falls on a Sunday, a response or other action taken the next business day, namely Monday, February 6, 2006, is considered timely under 37 C.F.R. § 1.7. Accordingly, this Brief is timely filed.

Under the provisions of 37 C.F.R. § 41.37, this Appeal Brief is being filed together with a check in the amount of $500.00 covering the 37 C.F.R. 41.20(b)(2) appeal fee. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 50-0872.

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REAL PARTY IN INTEREST

The assignee of record, Addition Technology, Inc., by virtue of an assignment recorded at Reel 011911, Frame 0395, is the Real Party In Interest.

RELATED APPEALS AND INTERFERENCES

No appeals or interferences are related to the subject appeal.

STATUS OF CLAIMS

Claims 23, 24, 28 and 30 to 44 are pending in the above-identified application. Claims 1 to 22, 25, 26, 27 and 29 have been canceled. Claims 38 and 39 have been withdrawn as a result of a requirement for restriction. Claims 23, 24, 28, 30 to 37 and 40-44, were finally rejected and are the subject matter of this Appeal.

STATUS OF AMENDMENTS

The claims have not been amended in reply to the Final Office Action.

SUMMARY OF CLAIMED SUBJECT MATTER

The claims of the subject application are directed to a device having a physiologically compatible, pliable, elongated, synthetic polymeric implant (page 10, line 24; page 11, lines 3 to 13) adapted for implantation within a human cornea (page 3, lines 21 to 24). Prior to implantation in the cornea, the implant comprises a plurality of adjoining sections and each is constructed to effect correction of a refractive disorder of the eye after implantation (page 20, lines 30 to 34). The cross-sectional area of implant changes substantially stepwise from one section to an adjoining section (page 20, lines

30 to 35 and Figure 16A) and which cross-sections increase in steps along the axis of the adjoining sections (page 21, lines 1 to 5).

The claims of the subject application also are directed to an insert precursor suitable for introduction into a human cornea (page 3, lines 21 to 24). The precursor has a physiologically compatible pliable member (page 10, line 24) having two ends and an elongated body extending there between. The body comprises at least two adjoining portions, at least one of which is constructed to effect correction of a refractive disorder of the eye after implantation (page 21, lines 31 to 35), the cross-sectional area of said member changing substantially from one portion to the next along the body and which cross-sections increase in steps along the axis of the adjoining sections (Figure 16 A; page 20, lines 30 to 34).

ISSUE ON APPEAL

Whether the Declaration Under 37 C.F.R. § 1.132 filed April 5, 2005 is sufficient to overcome the rejection of claims 23, 24, 28, 30 to 37 and 40 to 44 under 35 U.S.C. § 102(e) ?

ARGUMENT

The sole issue on Appeal is whether the Declaration Under 37 C.F.R. § 1.132 filed April 5, 2005, a copy of which is attached as Exhibit A, is sufficient to overcome the rejection of claims 23, 24, 28, 30 to 37 and 40 to 44 as allegedly anticipated under 35 U.S.C. § 102(e) by Silvestrini et al., U.S. Patent No. 5,300,118. The Office opined that the Declaration was defective because it lacked an unequivocal declaration by Mr. Silvestrini that he conceived or invented the subject matter disclosed in the patent and relied on in the Office's rejection. The Office argued that M.P.E.P. § 2136.05 indicates that there must be a showing or proving of a date of conception or invention by, for example, proving that the co-inventors of the patent were associated with Applicant and learned of the Applicant's invention from the Applicant or

showing that the applied patent disclosure arose from the Applicant's work coupled with a showing of conception by the Applicant before the filing date of the patent.

The Office also rejected Applicant's reliance on the facts of *In re Katz* on the ground that the facts of the instant case are not equivalent to the facts of *In re Katz* because in the instant application, the applied reference is a U.S. patent, so that the joint inventors are presumed to be the joint inventors of at least some of the subject matter disclosed therein.

Applicant's attorney traverses the rejections and directs the Board to the statements made by the Office on page 3, paragraph 3 of the Final Office Action. The reference paragraph is reproduced below for the Board's convenience:

> "The applied reference has a common inventor with the instant application. Based upon the earlier effective filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome by either a showing under 37 C.F.R. 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is not the invention "by another" or by an appropriate showing under 37 C.F.R. 1.131."

(Emphasis Added.)

Applicant's Declaration is consistent with the requirements of law and establishes that the "invention" disclosed but not claimed in the prior art patent was the invention of the inventor of the claims on appeal because the statements made by the Declarant Thomas A. Silvestrini serve the same purpose, *i.e.*, to aver that the "invention" disclosed but not claimed in the prior art is his sole invention. Paragraphs 1 through 3 of the Declaration state that:

> 1. I also am a named co-inventor of U.S. Patent No. 5,300,118 (the '118 Patent) attached to this Declaration. Therefore, the '118 Patent describes my own work. Mark Mathias and Bryan Loomas are named co-inventors of the '118 Patent.

2. I am the sole inventor of any subject matter disclosed in U.S. Patent No. 5,300,118 and claimed in the above-identified application. Mark Mathias and Bryan Loomas identified as my co-inventors in Paragraph 1, above, did not contribute to the claims of the subject application.

3. I am the true and sole inventor of the claimed subject matter in the subject application.

Thus, Applicant's Declaration establishes that the cited patent is not "by another" and therefore is not prior art against the subject application under 35 U.S.C. § 102(e). In addition, since U.S. Patent No. 5,300,118 was issued and therefore published after the effective filing date of the subject application, it cannot be used as prior art under either of 35 U.S.C. § 102 (a) or (b). Applicant thus respectfully requests that the Office remove the rejection of the claims under 35 U.S.C. § 102(e).

The rejection of the claims under 35 U.S.C. § 102(e) was the only remaining issue against the claims. Removal of the rejection places the claims in condition for allowance. Accordingly, the appealed claims are in condition for allowance and a notice to that effect is respectfully requested.

Respectfully submitted,

Date: February 6, 2006

By _____

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CLAIMS APPENDIX

I. LISTING OF THE CLAIMS

This Listing of the Claims supersedes all prior amendments, listings and versions of the Claims.

Claims 1 through 22 (Canceled).

23. (Previously Presented) A device comprising a physiologically compatible, pliable, elongated, synthetic polymeric implant adapted for implantation within a human cornea and having a configuration prior to implantation in the cornea, the implant comprising a plurality of adjoining sections each constructed to effect correction of a refractive disorder of the eye after implantation, the cross-sectional area of implant changing substantially stepwise from one section to an adjoining section and which cross-sections increase in steps along the axis of the adjoining sections.

24. (Previously Presented) The device of claim 23 wherein said device includes at least three of said sections, the cross-sectional areas of said at least two sections being substantially different.

Claims 25 through 27 (Canceled).

28. (Previously Presented) An insert precursor suitable for introduction into a human cornea, said insert precursor comprising a physiologically compatible pliable member having two ends and an elongated body extending there between, the body comprising at least two adjoining portions at least one of which is constructed to effect correction of a refractive disorder of the eye after implantation, the cross-sectional area of said member changing substantially from one portion to the next along the body and which cross-sections increase in steps along the axis of the adjoining sections.

Claim 29 (Canceled).

30. (Previously Presented) The insert precursor of claim 28, wherein a portion of the member is constructed to effect correction of a predetermined refractive disorder of an eye.

31. (Previously Presented) The insert precursor of claim 28, wherein the length of at least one of said portions is less than a circumference of the human cornea.

32. (Previously Presented) The insert precursor of claim 28, wherein the length of at least one of said portions approximates a circumference of the human cornea.

33. (Previously Presented) The insert precursor of claim 28, wherein the insert precursor has a modulus of elasticity less than about 3.5 kpsi.

34. (Previously Presented) The insert precursor of claim 28, wherein the cross-sectional area of said member changes substantially stepwise over a region from one portion to the next along the body.

35. (Previously Presented) The implant of claim 23 wherein, said sections having substantially different cross-sections from each other and having a modulus of elasticity less than about 3.5 kpsi, at least one of said sections being adapted to effect correction of a refractive disorder of the eye.

36. (Previously Presented) The implant of claim 35 wherein said at least one section has a modulus of elasticity between 1 psi and 1 kpsi.

37. (Previously Presented) The implant of claim 36 wherein said at least one section has a modulus of elasticity between 1 psi and 500 psi.

38. (Withdrawn) A method for effecting a refractive correction of the human cornea, comprising:

implanting at least a portion of at least one section of an implant, having multiple sections each having a different cross-sectional area, into the cornea,

and allowing at least another one of said sections to be exterior to the cornea; and

removing said at least another one of said sections exterior to the cornea from the implanted portion of the implant.

39. (Withdrawn) The method of claim 38, wherein at least two sections of said implant are exterior to the cornea after said implanting and wherein said removing includes removing said at least two sections of said implant from the implanted portion of the implant.

40. (Previously Presented) The device of claim 23 wherein each of said sections is arcuate.

41. (Previously Presented) The device of claim 23 wherein the sections are axially contiguous.

42. (Previously Presented) The insert precursor of claim 28 wherein said insert precursor is arcuate.

43. (Previously Presented) The insert precursor of claim 28 wherein said at least two adjoining portions are axially contiguous.

44. (Previously Presented) The insert precursor of claim 23, wherein each of the sections adjoining the section having the cross-sectional area effective to correct the refractive disorder after implantation are removable after implantation.

Atty. Dkt No: AT 2021.20

Certificate of Mailing/Transmission (37 C.F.R. § 1.8):

[X] Pursuant to 37 C.F.R. § 1.8, I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

[ ] Pursuant to 37 C.F.R. § 1.6(d), I hereby certify that this paper and all enclosures are being sent via facsimile on the date indicated below to the attention of Examiner Rebecca E. Prouty at Facsimile No. (703) 308-4242

Dated: 3/31, 2005 Name of Person Certifying: Peggy Nichols
Printed Name: PEGGY NICHOLS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Thomas A. Silvestrini	Examiner:	David H. Willse
Filing Date:	July 15, 1996	Group Art Unit:	3738
Serial No.:	08/596,221	Confirmation No.:	5679
Title:	**SEGMENTED PLIABLE INTRASTROMAL CORNEAL INSERT**		

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

DECLARATION OF THOMAS A. SILVESTRINI UNDER 37 C.F.R. § 1.132 (*IN RE KATZ*)

Sir:

I, Thomas A. Silvestrini, named as the sole inventor of the above-identified application, hereby declare as follows:

1. I also am a named co-inventor of U.S. Patent No. 5,300,118 (the '118 Patent) attached to this Declaration. Therefore, the '118 Patent describes my own work. Mark Mathias and Bryan Loomas are named co-inventors of the '118 Patent.
2. I am the sole inventor of any subject matter disclosed in U.S. Patent No. 5,300,118 and claimed in the above-identified patent application. Mark Mathis and Bryan Loomas identified as my co-inventors in Paragraph 1 above, did not contribute to the claims of the subject application.

3. I am the true and sole inventor of the subject matter claimed in the subject application.

4. I further declare that all statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 3/30/05

Thomas Silvestrini

Thomas A. Silvestrini

U.S.S.N: 08/596,221
Attorney Docket No: AT 2021.20